UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

In Re: PHARMACEUTICAL INDUSTRY

AVERAGE WHOLESALE PRICE

LITIGATION

THIS DOCUMENT RELATES TO:

State of Montana v. Abbott Labs., Inc. et al.

02-CV-129804-PBS

State of Nevada v. American Home Products, Corp., et al.

02-CV-12086-PBS

MDL NO. 1456

Master File No. 01-CV-12257-PBS

Judge Patti B. Saris

MEMORANDUM OF LAW IN SUPPORT OF ASTRAZENECA PHARMACEUTICALS LP'S MOTION TO DISMISS THE STATE OF MONTANA'S SECOND AMENDED COMPLAINT AND THE STATE OF NEVADA'S AMENDED COMPLAINT

AstraZeneca Pharmaceuticals LP ("AstraZeneca")¹ respectfully submits this memorandum of law in further support of its motion to dismiss the State of Montana's Second Amended Complaint ("Montana Complaint") and the State of Nevada's Amended Complaint ("Nevada Complaint") (collectively, the "Amended Complaints"). As set forth in defendants' consolidated memorandum of law ("Consolidated Memorandum"), the Amended Complaints should be dismissed in their entirety because (i) the claims asserted are preempted; (ii) the Amended Complaints fail to state a claim under the various state statutes asserted; and (iii) plaintiffs' fraudbased claims fail to satisfy the pleading requirements of Rule 9(b) with respect to all defendants. As explained below, if the Amended Complaints are not dismissed in their entirety, the claims

¹ The entity identified in the complaints as AstraZeneca US does not exist. Although mentioned in the complaints, AstraZeneca PLC is not a defendant in these actions.

against AstraZeneca should, at a minimum, be limited to claims relating to a single drug – Zoladex® (goserelin acetate implant).

ALLEGATIONS OF THE AMENDED COMPLAINTS

In the Amended Complaints, Montana and Nevada assert a variety of state claims against AstraZeneca, based on two types of alleged misconduct: 1) the fraudulent reporting of false and inflated average wholesale prices ("AWPs") for certain drugs; and 2) the failure to report the "best price" for certain drugs, as required by the federal Medicaid Rebate statute. Nevada Complaint ("Nev. Cplt.") ¶¶ 139-143, 392-400; Montana Complaint ("Mont. Cplt.") ¶¶ 176-80, 612-16. Montana and Nevada further allege that AstraZeneca's alleged misconduct extends to seventeen AstraZeneca drugs. Nev. Cplt. ¶ 194; Mont. Cplt. ¶ 249.² Although these seventeen AstraZeneca drugs and their published AWPs are nominally identified in the Amended Complaints, see Nev. Cplt. ¶ 194 & App. A; Mont. Cplt. ¶ 249 & App. A, there are no other factual allegations in the Amended Complaints relating to any of these drugs, except Zoladex. See Nev. Cplt. ¶¶ 194-218, 398-400; Mont. Cplt. ¶¶ 249-73, 628-30.

ARGUMENT

THE MAJORITY OF PLAINTIFFS' CLAIMS AGAINST ASTRAZENECA MUST BE DISMISSED PURSUANT TO RULE 9(B)

Rule 9(b) requires that a plaintiff plead the "who, what, where, and how" of the alleged fraud. See United States ex rel. Franklin v. Parke-Davis, 147 F. Supp. 2d 39, 46 (D. Mass. 2001). Moreover, in the similar context of defendants' motions to dismiss the Master Consolidated Class Action Complaint, this Court held that plaintiffs must also allege "the allegedly fraudulent AWP for each drug" in order to state a claim with respect to that drug. In re Pharmaceutical Indus. Average Wholesale Price Litig., 263 F. Supp. 2d 172, 194 (D. Mass. 2003). With respect to the majority of

² The seventeen drugs are: Accolate, Armidex, Atacand, Atacand HCT, Casodex, Diprivan, Entocort, Nexium, Nolvadex, Prilosec, Pulmicort, Rhinocort, Seroquel, Toprol, Zestril, Zoladex and Zomig.

their claims against AstraZeneca, Montana and Nevada have failed to satisfy this Court's standard and Rule 9(b). Accordingly, these claims – whether based on an AWP or Best Price theory – must be dismissed pursuant to Rule 9(b).

Plaintiffs allege that AstraZeneca manufactures "several drugs" reimbursable under the Montana and Nevada Medicaid Programs, Mont. Cplt. ¶ 39; Nev. Cplt. ¶ 33, but fail to allege any fraudulent conduct by AstraZeneca relating to any drug other than Zoladex. Indeed, no drug other than Zoladex is even mentioned in the section of the States' Amended Complaints devoted to AstraZeneca. Mont. Cplt. ¶¶ 249-73; Nev. Cplt. ¶¶ 194-218. Moreover, plaintiffs do not even attempt to allege a "fraudulent AWP" for any drug other than Zoladex. Instead, plaintiffs have merely reprinted the published AWPs for these other drugs. This regurgitation of the published AWP is plainly insufficient to establish any claims against AstraZeneca based on these drugs, because there are no specific allegations demonstrating how these published AWPs are fraudulent.

Similarly, there are no allegations in the Amended Complaints relating to AstraZeneca's reporting of "best price" for any drug other than Zoladex. Although sixteen other AstraZeneca drugs are named in the complaints, there are no allegations at all, much less particularized allegations, with respect to any of these drugs relating to "fraudulent" best price reports or the "discounts and other inducements" that allegedly resulted in false prices being reported to the Medicaid program. General, conclusory allegations about unspecified defendants and drugs, see Nev. Cplt. ¶¶ 392-96; Mont. Cplt., ¶¶ 612-15, are not sufficient to state a claim against AstraZeneca relating to the sixteen AstraZeneca drugs other than Zoladex that are identified in the Amended Complaints.

Furthermore, plaintiffs' conclusory allegations regarding recent governmental investigations are insufficient to support a best price claim regarding Zoladex. Mont. Cplt. ¶¶ 629-30; Nev. Cplt.

¶¶ 399-400. As discussed in the Consolidated Memorandum, plaintiffs fail to identify even one allegedly false best price report for any drug, including Zoladex.

Accordingly, the majority of plaintiffs' claims against AstraZeneca – whether based on an "AWP" or "Best Price" theory – fail to satisfy the particularity requirement of Rule 9(b).

CONCLUSION

For the reasons set forth above and in the Consolidated Memorandum, the claims against AstraZeneca should be dismissed; in the alternative, they should be limited to Zoladex.

Dated: Boston, Massachusetts September 15, 2003

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I certify that on September 15, 2003, a true and correct copy of the foregoing Memorandum in Support of AstraZeneca Pharmaceuticals LP's Motion to Dismiss the State of Montana's Second Amended Complaint and the State of Nevada's Amended Complaint was served on all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2 by sending a copy to Verilaw Technologies for posting and notification to all parties.

Lucy Fowler